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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,048	08/09/1999	NAPHTALI SAVION	26775U	4662
20529 7590 01/23/2009 THE NATH LAW GROUP 112 South West Street Alexandria, VA 22314				
EXAMINER				
FAY, ZOHREH A				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
01/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/341,048

**Applicant(s)**

SAVION ET AL.

**Examiner**

ZOHREH A. FAY

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/17/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 141-146, 148, 150-168, 170-175, 179 and 181-208 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 141-146, 148, 150-168, 170-175 and 179-208 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/17/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Claims 141-146, 148, 150-168, 170-175, 179 and 181-208 are presented for examination.

The remarks filed on have been received and entered.

Claim 204 is rejected under 35 U.S.C. 112 second paragraph as to the trade name "Intralipid" for the reasons set forth on pages 2-3 of the office action of April 17, 2008.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 141-146, 148, 150-168, 170-175, 179 and 181-208 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 141-146, 148, 150-168, 170-175, 179 and 181-208 are indefinite as to the phrase "A method of promoting healing or regeneration of damaged eye epithelium or cornea or of the anterior segment of the eye". Such phrase is directed to regeneration of cornea, eye epithelium or anterior segment of the eye. It is unclear as to how a compound can regenerate different parts of the eye. The instant specification fails to show how the regeneration of all the cells and segments are done. Claims 193 and 202 are indefinite as to the term "including". Such term fails to set forth the other type of damage intended.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 141-146, 148, 150-168, 170-175, 179 and 181-208 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to "A method of promoting healing or regeneration of damaged eye epithelium or cornea or the anterior segment of the eye administering or applying to a subject. Afflicted with a disorder or condition associated with eye epithelium, cornea or anterior segment damage". Such method is directed to the treatment of unspecified disorder and no evidence indicates that the treatable disease was known to the applicant. In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 154 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating corneal epithelium damage, does not reasonably provide enablement for preventing or curing damaged eye epithelium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to "curing or prevention" of the invention commensurate in scope with these claims. The factors to be considered whether a

disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of promotion of healing or regeneration of damaged eye epithelium, which comprises alleviation, or curing or prevention thereof.

2) The state of the prior art:

The state of the art does not recognize that the prevention or cure of the claimed disorders is done easily. According to Wikipedia, tree Encyclopedia, there is no specific treatment for Steven-John syndrome. Such condition is a skin disorder, which can be life threatening. The corticosteroids, cyclophosphamide and cyclosporine and topical anesthetics are considered beneficial for such condition. The above source is silent as to the prevention or cure of such condition

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the alleviation, curing or prevention of damaged epithelium cells.

6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for the treatment of certain conditions associated with damaged epithelial cells using the claimed compounds. However the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims, which as stated above, are broad and encompass the alleviation, curing or prevention of damaged eye epithelium..

7) The presence or absence of working examples;

The examples in applicant's specification are drawn to the treatment of damaged eye epithelium cells. There are no examples drawn to the prevention or curing damaged eye epithelium cells.

8) The quantity of experimentation necessary;

Since examples in the specification are drawn to the use of the claimed compounds for the treatment of damaged eye epithelium cells, one skilled in the art would be burdened with undue experimentation to determine the effect of the claimed compounds on preventing or curing the damaged eye epithelium cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zohreh A Fay/  
Primary Examiner, Art Unit 1612